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APPLICATION	NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,990)	01/09/2002	Geza Bruckner	22740-1A	7684
24256	7590	03/22/2002			
		SHOHL, LLP	EXAMINER		
1900 CHEMED CENTER 255 EAST FIFTH STREET				NGUYEN, HELEN	
CINCINNATI, OH 45202		Н 43202		ART UNIT	PAPER NUMBER
				1617	
				DATE MAILED: 03/22/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	10/042,990	BRUCKNER ET AL.					
Office Action Summary	Examin r	Art Unit					
	Helen Nguyen	1617					
The MAILING DATE of this communication appears on the c ver sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM							
THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on <u>09 J</u>	<u>anuary 2002</u> .						
2a) ☐ This action is FINAL . 2b) ☐ Thi	s action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>3, 4, 6-8, and 29-47</u> is/are pending in the application.							
4a) Of the above claim(s) 31-34 and 38-47 is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>3-4,6-8,29,30 and 35-37</u> is/are rejected.							
7) Claim(s) is/are objected to.	7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) All b) Some * c) None of:							
 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 							
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 							
Attachment(s)							
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)					

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DETAILED ACTION

The claimed priority of this application to a divisional of US Application No. 09/512,577, filed February 24, 2000, now is US Patent No. 6,359,017, through a US Provisional Application No. 60/121,338, filed February 24, 1999, is acknowledged.

The preliminary amendment of paper no. 2, filed January 09, 2002, is acknowledged.

Claims 1, 2, 5 and 9-28 are canceled.

Claims 3, 4, and 6-8 are amended.

Claims 29-47 are newly added.

Claims 3, 4, 6-8, and 29-47 are pending.

Restriction/Election

This application contains claims directed to the following patentably distinct species of the claimed invention: **A**/ claims 3-4, 6-8, and 29-37 comprising phytoestrogen, phytoandrogen; **B**/ claims 38-47 comprising estrogen, androgen.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted

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if no generic claim is finally held to be allowable. Currently, compositions are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the

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evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Elections of species

patentably distinct species comprising third components. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 34-35 (exemplary) are generic to a plurality of disclosed patentably distinct species comprising <u>food bases</u>. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claims 3, 8, and 36 are generic to a plurality of disclosed patentably distinct species comprising <u>phytoestrogens</u>. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants must elect one ultimate species.

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During a telephone conversation with Rebecca Brown on Monday
March 18, 2002 a provisional election was made with traverse to prosecute
the invention of **A**/ comprising phytoestrogen, phytoandrogen, claims 3-4,
6-8, and 29-37; species: carnitine (claim 30), cereal (claim 35), and
genistin. Affirmation of this election must be made by applicant in replying
to this Office action. Claims 31-34, and 38-47 are withdrawn from further
consideration by the examiner, 37 CFR 1.142(b), as being drawn to a nonelected invention.

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Co-operation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

Claims 3-4, 6-8, 29-30, and 35-37 are presented for examination.

Specification objection

The disclosure is objected to because of the following informalities:

On page 1 of the specification, line 2 of the first paragraph, it appears that there is a typographical error on "§ 199". In addition, on line 1, it is suggested to insert "now US Patent No. 6,359,017 B1" following US Application Serial No. 09/512,577.



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Appropriate correction is required.

Claim rejection

- ❖ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-4, 6-8, 29-30, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 98/04248) in view of Fort (DE 29805782U1).

Jackson et al. teach a dietary supplement composition for post-menopausal women containing 1-50 mg phytoestrogen (abstract; page 7, line 27; and page 27, line 30). Genistin is specified (page 26, line 12). The composition may be formulated with cereal (page 27, line 11). Phytoestrogen obtaining from soybean is disclosed (page 27, line 30; and claim 47).

However, Jackson et al. do not teach carnitine.



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Fort teaches a dietary cereal containing carnitine (title, abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add carnitine to the composition of Jackson et al. to achieve the beneficial effect of supplementing the dietary needs for post-menopausal women.

As to the claimed weight percent, it is within the skill in the art to select optimal parameters such as ratios or weight percents of components in order to achieve a beneficial effect. See <u>In re Boesch</u>, 205 USPQ 215 (CCPA 19880). Therefore, the ratios or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Conclusion

Claims 3-4, 6-8, 29-30, and 35-37 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly



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owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Helen Nguyen Patent Examiner

March 21, 2002

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